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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,970

Applicant(s)

MARKHAM ET AL.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,9,11,12,14,25-27,29 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) 9,11,12,14,25-27 and 31-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,29 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 19 December 2005 in response to the Non-Final Office Action mailed 18 August 2005. Claims 9, 11, 12, 14, 25-27 and 31-46 had been withdrawn from consideration and claims 1, 4, 7 and 29 were considered in the 18 August Office Action. Claims 1, 4, 7, 26 and 29 were amended and claim 47 was added in the 19 December Paper. Claims 1, 4, 7, 9, 11, 12, 14, 25-27, 29 and 31-47 are pending and claims 1, 4, 7, 29 and 47 are under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 1 and 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record is **withdrawn** in view of the amendment of claim 1 such that the latency promoter is limited to comprising specific fragments of the sequence set forth as SEQ ID NO:1.

Claims 7 and 29 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record.

The previous Office Actions assert that the skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of any nucleic acid nucleic acid having at least 95% homology to SEQ ID NO: 1 and “essentially the same biological properties as the disclosed latency

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promoter”. The Office contends that only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph.

In response to the *prima facie* case and arguments of record, Applicant has amended claim 7 such that “the latency promoter is encoded by at least 630 bp and up to 2,000 bp of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of HVS as set forth in SEQ ID NO: 1.” Applicant submits that the skilled artisan would be able to readily envision a genus of nucleotide sequences having characteristics recited in the claims based on the disclosure.

These arguments have been fully considered but are not deemed persuasive. As stated in the 18 August Office Action (page 3) the claims do not require that the claimed nucleic acid comprise any of the sequence set forth as SEQ ID NO: 1. Instead, the claims can be broadly construed as limited to a nucleic acid comprising a latency promoter encoded by 630 bp and up to 2,000 bp of a (any) nucleic acid sequence immediately upstream of an (any) initiation codon of ORF73, wherein the initiation codon is set forth in SEQ ID NO: 1. The application clearly does not describe a latency promoter commensurate with the scope of what is now claimed. For reasons of record, only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant’s arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

Claims 1, 4, 7 and 29 **stand rejected** and newly added claim 47 **is rejected** under 35 U.S.C. 102(b) as being anticipated by Nicholas *et al.* (1992) *Virol.* 188:296-310 as evidenced by Entrez Nucleotide Database Accession No. M86409 for reasons of record and as further evidenced by pUC18, pUC19: description & restriction map, available at www.fermentas.com/techinfo/nucleic_acids/mappuc1819.htm.

In response to the *prima facie* case and arguments of record, Applicant has amended claim 1 to recite “wherein the latency promoter is operatively linked to a heterologous gene and is capable of driving expression of said heterologous gene, and wherein the latency promoter is encoded by a specific sequence of SEQ ID NO: 1”.

In the remarks (bridging pages 9-10) Applicant contends that the claims are not anticipated by the art because Nicholas *et al.* does not discuss a latency promoter or its use to drive expression in human cells as is disclosed in the present application. Applicant urges that there is no indication in Nicholas *et al.* of function or of a promoter that can be used when operatively linked, to drive heterologous gene expression in human cells.

These arguments have been fully considered but are not deemed persuasive. It is first noted that claims 7 and 29 do not recite the limitations that Applicant asserts distinguish the instant claims from the prior art. Therefore, claims 7 and 29 stand rejected for reasons of record.

With regard to claims 1, 4 and 47, which do recite, “the latency promoter is operatively linked to a heterologous gene and is capable of driving expression of said heterologous gene, and wherein the latency promoter is encoded by a specific sequence of SEQ ID NO: 1”, these

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limitations do not distinguish the claimed invention from the teachings of Nicholas *et al.*

Applicant's arguments appear to be based on an assumption that the claims require the claimed nucleic acid be configured such that the latency promoter is driving expression of a heterologous gene. However, as the specification does not contain a limiting definition of "operably linked", the limitation "operably linked to a heterologous gene" encompasses operable linkage in any way. The nucleic acid comprising an HVS promoter disclosed in Nicholas *et al.* is comprised within a pUC19 vector (see especially the second full paragraph on page 297), which vector comprises a beta-lactamase selectable marker gene (*bla*; see especially the pUC19: description and restriction map). The selectable marker gene is "operably linked" to the nucleic acid encoding the latency promoter insofar as the selectable marker provides for selection of host cells comprising the vector, which vector comprises the promoter.

With regard to the limitation, "capable of driving expression of said heterologous gene", the broadest reasonable interpretation of the limitation is that the promoter has the inherent ability to drive expression of the heterologous gene. In other words, the limitation does not require that the claimed nucleic acid be configured such that the latency promoter is driving expression of the heterologous gene, but that the latency promoter comprised by the nucleic acid have the capability to drive expression of a heterologous gene if configured to do so. As the nucleic acid of Nicholas *et al.* comprises the same sequence as the nucleic acid of the instant claims, the promoter activity would be "capable of" driving expression of the heterologous *bla* gene if configured to do so. Therefore, the teachings of Nicholas *et al.* anticipate the claims afforded their broadest reasonable interpretation in light of the specification.

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Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §102 as anticipated by Nicholas *et al.*

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states, “[w]henver the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not

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described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, the claims recite that the isolated nucleic acid comprises a latency promoter comprising specific fragments of SEQ ID NO: 1 (e.g., 630 bp of nucleotides 4-633 of SEQ ID NO: 1). With regard to support for this limitation, Applicant’s remarks provide only the vague assertion, “Support for this amendment can be found throughout the specification and claims as originally filed” (third full paragraph on page 9). However, upon reviewing the originally filed disclosure, the Examiner can find no literal support for the specific sequence limitations recited in the claims and it is unclear whether the fragments described, *inter alia*, in the first full paragraph on page 17, comprise the sequence fragments recited in the claims. Therefore, limitation of the promoter to comprising 630 bp of nucleotides 4-633 of SEQ ID NO: 1 or nucleotides 4-2003 of SEQ ID NO: 1 constitutes impermissible new matter.

It is noted that implicit support for the limitations might be established by a teaching demonstrating that the PCR primers discussed in the first full paragraph on page 17 would provide the fragments of SEQ ID NO: 1 recited in the instant claims. If Applicant can identify such a teaching, this rejection would be overcome.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636



DANIEL M. SULLIVAN
PATENT EXAMINER